

Appl. No. : 09/579,327  
Filed : May 25, 2000

### REMARKS

Claim 1 has been amended to clearly recite the claimed invention.

The changes made to the Claims by the current amendment, including [deletions] and additions, are shown on an attached sheet entitled VERSION WITH MARKINGS TO SHOW CHANGES MADE, which follows the signature page of this Amendment.

#### Support for Amended Claim 1

Claim 1 has been amended to recite that the peptidoglycan is treated with an acid having a pH less than about 7.0. Applicants submit that one of skill in the art would know that acids have a pH less than about 7.0. In addition, since the action of the acid on the peptidoglycan is non-specific, it is simply hydrolyzing the bonds, one of skill in the art would know that any type of acid would work. Thus, Applicants submit that there is support for the amendment.

#### Rejection under 35 U.S.C. §112, second paragraph

The Examiner has rejected Claims 1-21 under 35 U.S.C. §112, second paragraph as being vague in the recitation of "acceptable pH" is maintained. The Examiner believes that one of skill in the art would not know what constitutes a physiologically acceptable pH.

However, Applicants submit that just as one of skill in the art would know that an acid has a pH of less than about 7.0, he or she would know that a physiologically acceptable pH may be dependant upon the site of administration, but is usually about 7.0. One of skill in the art would also know that if the administration is topically, a less stringent range would be warranted.

#### Rejection under 35 U.S.C. §102(b)

The Examiner has rejected Claims 1-4, 6, 8-9, and 14 as being anticipated by Matsuzaki et al because the Examiner believes that, like the claimed invention, Matsuzaki treats the peptidoglycan extracts with an acid. The Examiner cites the abstract and the second column in Matsuzaki et al. as support for the recitation of an acid. However, Applicants respectfully submit that the Examiner is incorrect. The abstract states that the active ingredient is a: "polysaccharide-glycan complex obtained by treating a Gram-positive bacteria such as lactic acid bacteria ...". The lactic acid refers only to the fact that the bacteria is a type of bacteria which produces lactic

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acid when grown in milk. This does not mean that the peptidoglycan from this bacteria was treated with an acid. In fact, it was not. The peptidoglycan in Matsuzaki et al was only treated with a specific enzyme, from the bacteria belonging to the genus *Achromobacter*.

The Examiner further cites the use of hydrochloric acid at a pH of 8.0 in column 2 of Matsuzaki, et al. However, column 2, lines 23-24 reads: "Heat dead cells (1.5 g) of a lactic acid bacterium was suspended in 150 ml of a 10 mM: tris-HCl buffer (pH 8.0), and 100,000 units of Achromopeptidase (TBL-1) ...". Tris-HCl as recited in this passage is a buffered salt solution at a pH of 8.0. this is not an acid as the definition of an acid is a solution with a pH of below 7.0. In addition, this again recites that the peptidoglycan was treated only with the enzyme achromopeptidase.

Therefore, Matsuzaki, et al. teaches only treating peptidoglycan with the enzyme achromopeptidase and does not suggest or teach the treatment with an acid. Thus, Matsuzaki et al. does not anticipate the claimed invention and Applicants respectfully request withdrawal of the rejection under U.S.C. §102(b).

#### **Rejection under 35 U.S.C. §103(a)**

The Examiner has rejected claims 1, 11-12, 16, and 19 under 35 U.S.C. §103(a) as being unpatentable over Matsuzaki et al. in view of Converse et al.

The Examiner believes that Matsuzaki et al. teaches treating peptidoglycan with an acid and Converse et al teaches the removal of lipids using chloroform.

However, as stated in the Rejection under 35 U.S.C. §102(b), Matsuzaki, et al does not teach or suggest the treatment of peptidoglycan with an acid, but only the treatment of peptidoglycan with the enzyme Achromopeptidase. Thus, since Converse et al does not teach the treatment of peptidoglycan with an acid, all of the claimed elements are not taught by the combination of Matsuzaki et al and Converse et al. Thus, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

#### **Telephonic Interview of November 19, 2001**

Applicants would like to thank the Examiner for the interview of November 19, 2001 in which the Matsuzaki reference was discussed and it was agreed that the Matsuzaki reference did not teach the treatment of peptidoglycan with an acid.

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**Conclusion**

Should there be any questions in connection with the above-captioned patent application, the Examiner is respectfully requested to contact the undersigned at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Apr. 23 2002

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1. (Amended) A method for producing an immune stimulating composition comprising:  
treating bacteria containing peptidoglycan with [acid wherein said acid has a pH  
of between about pH 1 and about ]an acid having a pH less than pH 7;  
removing large cellular components from the solution resulting from said treating;  
and  
saving the remaining solution and adjusting the pH to a physiologically acceptable  
pH.